

REMARKS

Claims 21 through 49 were pending in the application. By this amendment, claims 21, 43, 47, and 48 have been amended. Reconsideration and withdrawal of the rejections is requested in view of the foregoing changes to the claims and the following remarks.

The following remarks are intended to address all of the grounds for rejecting the claims set forth in the pending Office Action.

I. Claim Rejections under 35 U.S.C. § 103(a)

Claims 21-25, 36, 37, and 40-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sonnenschein et al. (US 2001/0056282) in view of El Gazayerli (USP 6,159,146) and further in view of Sauer et al. (USP 6,996,931). In addition, claims 26-35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sonnenschein, El Gazayerli, and Sauer in further view of Kalloo et al. (US 2002/0022851). Also, claims 38 and 39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sonnenschein, El Gazayerli, and Sauer in further view of Reed (US 2003/0165887). Claims 43-47 were rejected over the combination of Sonnenschein and El Gazayerli. Finally, claims 48-49 were rejected over the combination of Sonnenschein and El Gazayerli in further view of Kalloo. Without acceding to the grounds for rejecting the claims, Applicant responds as follows.

To establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35

U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

A. Claims 21-42

Claim 21 recites a method for performing a medical procedure that includes, *inter alia*, the steps of advancing an overtube within a hollow body organ in a flexible state, transitioning the overtube to a rigid state, advancing a plication device through the overtube, and forming a tissue fold within the hollow body organ with the plication device. By the present amendment, claim 21 has been amended to recite that the plication device is advanced through “a lumen defined by” the overtube, and that the plication device comprises “a pair of movable jaws adapted to engage tissue within the hollow body organ.” Support for these amendments is provided throughout the specification, such as, for example, at paragraphs 0079 and 0253, and at FIGS. 2A-B and 40A-D.

The Sonnenschein publication, on the other hand, does not describe or suggest a method that includes the recited steps of:

- advancing “an overtube comprising a plurality of nested elements” within the hollow body organ;
- transitioning the overtube to a rigid state “by imposing a load that clamps the contoured surfaces of adjacent nested elements together;”
- advancing a plication device “through a lumen defined by” the overtube;
- advancing a plication device “after the overtube has been transitioned to the rigid state;” or
- a plication device “comprising a pair of movable jaws adapted to engage tissue within the hollow body organ.”

The Office Action (at pages 2-3) identifies the insertion tube 48 of a conventional endoscope 40 described at paragraph 0162 of the Sonnenschein publication as corresponding with the recited overtube, and a stapling assembly 61, 61A as corresponding with the recited plication device. Sonnenschein, however, does not describe or suggest advancing the stapling assembly 61, 61A “through a lumen” of the endoscope 40, nor does it describe or suggest advancing the stapling assembly 61, 61A

"after the [endoscope 40] has been transitioned to the rigid state." Finally, the stapling assembly 61, 61A of the Sonnenschein device does not include the recited "pair of movable jaws adapted to engage tissue within the hollow organ."

Figure 5 of the Sonnenschein publication is reproduced below to the right. The Office Action states that "the plication device [i.e., the stapling device 61, 61A] is advanced through the overtube [i.e., the endoscope 40] in the manufacturing process since when the overtube is placed into the stomach it already contains the plication device." This statement is both a mischaracterization of the description contained in the Sonnenschein publication and an unreasonable interpretation of the limitations recited in claim 21. As to the former, nowhere does Sonnenschein describe the "manufacturing process" of the stapling device, much less whether the stapling elements 61, 61A are "advanced ... through" the endoscope 40 during that process. These stapling elements 61, 61A include an anvil and a staple cartridge, (see, e.g., FIGS. 26A-B), which occupy fixed positions on the endoscope. There is, therefore, no reason to speculate that these components would be "advanced through" the endoscope during the manufacturing process, rather than simply being located and attached at their respective positions on the device.

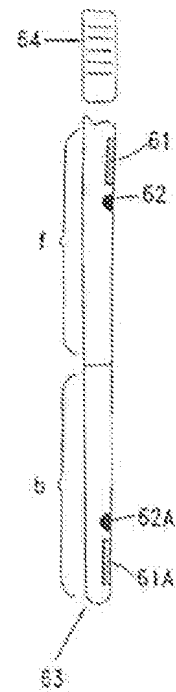


Fig. 5

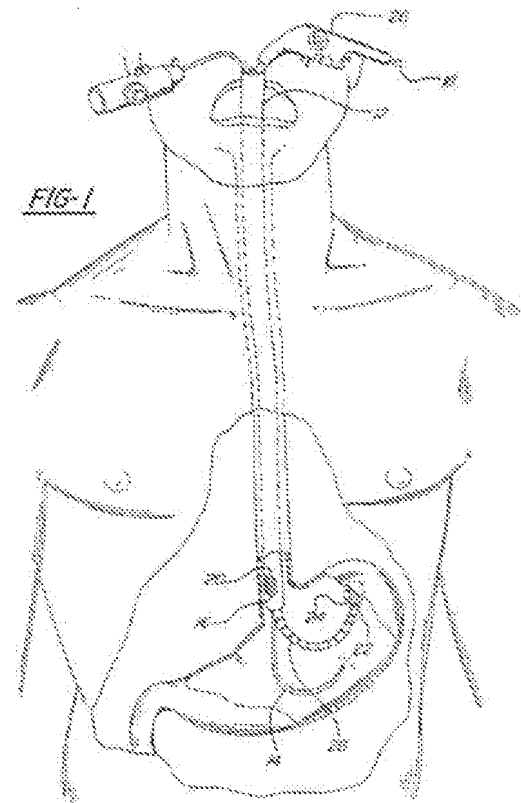
Moreover, even if the "manufacturing process" of the Sonnenschein device was as described in the Office Action, the proposed interpretation of the "advancing a plication device" limitation of claim 21 to read on a step of a device manufacturing process is entirely unreasonable. During examination, the Office determines the scope of application claims not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004). In this case, the "advancing a plication device" limitation plainly and reasonably refers to a step of a medical procedure, not of a manufacturing process. For at least these reasons, the Sonnenschein publication fails to describe or suggest the above-referenced limitations recited in claim 21.

The El Gazayerli and Sauer patents and the Kalloo and Reed publications do not correct the deficiencies of the Sonnenschein publication. None of these references describes a method that includes the steps of advancing a plication device through a lumen of an overtube comprising nested elements after the overtube has been transitioned to a rigid state, and in which the plication device includes a pair of movable jaws adapted to engage tissue. The Office Action contains several errors in its attempts to show otherwise.

For example, the Office Action states (at pp. 5-6) that El Gazayerli discloses a method that includes the step of "advancing an overtube comprising a plurality of nested elements" into a hollow body organ.

The Office Action contends that the fastening device 16 of the El Gazayerli apparatus constitutes an "overtube" that includes "nested elements" in the form of a linkage 28, and from there concludes that it would have been obvious to substitute the "art-recognized equivalent" linkage 28 for the endoscope of the Sonnenschein device. But El Gazayerli's fastening device 16 having a linkage 28 is not an "overtube" through which a plication device is advanced.

On the contrary, El Gazayerli's fastening device 16 is itself advanced through a "flexible elongated conduit 12" that extends through the esophagus of the patient. (See FIG. 1 above). The conduit 12, however, does not "comprise a plurality of nested elements." The Office Action is essentially attempting to draw an equivalence between non-equivalent components of the Sonnenschein and El Gazayerli systems, and then propose a substitution of one for the other. This is not a sufficient basis for establishing a prima



facie case of obviousness. Accordingly, the combination proposed in the Office Action is not supported by the teachings of the references.

As another example, in discussing the Sauer patent, the Office Action contends (at pp. 7-8) that:

- Sonnenschein teaches “a single device that is inserted into the body of the patient instead of two separate components where one is inserted prior to the other one.”¹
- Sauer shows a plication device which can be inserted as a single device or through an overtube; and
- “because the insertion means were art-recognized equivalents,” one of ordinary skill in the art would have found it obvious to use an endoscope working channel or an accessory tube instead of inserting a single device.

There is no support for the broad contention that Sauer’s insertion means were “art-recognized equivalents” for all purposes. While the Sauer patent may describe multiple embodiments of its disclosed devices, there is nothing to suggest that this teaching is universally applicable, nor that it is applicable to the Sonnenschein device and method. Moreover, even if this contention were true, it does nothing to support a prima facie case of obviousness of any of the pending claims. The combination of Sonnenschein, El Gazayerli, and Sauer still fails to teach the above-identified limitations recited in claim 21.

As yet another example, in the rejection of claim 26, at page 9, the Office Action states that Sonnenschein does not describe forming “a plurality of folds in the patient’s stomach,” but that it would have been obvious to do so because “it would be necessary for the particular procedure to have several folds in order to reduce the size of the stomach.” This is pure hindsight, using the Applicant’s claims as a guide, and is therefore improper. Sonnenschein describes a fundoplication apparatus and method having nothing to do with “reducing the size of the stomach.” The Office Action goes on to incorporate the Kalloo publication, stating that Kalloo shows a “plurality of folds

¹ This itself contradicts the earlier contention (at page 3 of the Office Action) that Sonnenschein teaches advancing a plication device (i.e., a first component) through an overtube (a second component) “in the manufacturing process.”

performed in a gastric reduction procedure,” and that it would have been obvious to apply Kalloo to the combined teachings of Sonnenschein, El Gazayerli, and Sauer “to reduce the total size of the stomach.” There is simply no support for this conclusion because Sonnenschein, the primary reference, *is not concerned with* reducing the total size of the stomach. “To draw on hindsight knowledge of the patent invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction – an illogical and inappropriate process by which to determine patentability.” *Sensonic Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996), citing *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). “The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made.” *Id.*, citing *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985). Nothing in the cited art suggests the proposed combination of references to reach Applicant’s claim.

Accordingly, because at least the foregoing elements recited in claim 21 are not disclosed, taught, or suggested by the Sonnenschein publication or by the combination of Sonnenschein with any of the other cited references, and because the Office Action fails to set forth an appropriate foundation for combining the references in the manner proposed in the Office Action, there can be no *prima facie* case of obviousness of claim 21. The claim, and all of its dependent claims (i.e., claims 22-42), should be allowed.

B. Claims 43-49

Turning to claim 43, that claim recites a method for performing a medical procedure that includes, *inter alia*, the steps of advancing a main body having a plication device within a hollow body organ in a flexible state, transitioning the main body to a rigid state, and forming a tissue fold within the hollow body organ with the plication device. By the present amendment, claim 43 has been amended to recite that the plication device is “extendable from” a distal region of the main body, and that the plication device comprises “a pair of movable jaws adapted to engage tissue within the hollow body organ.” Support for these amendments is provided throughout the

specification, such as, for example, at paragraphs 0079 and 0253-0257, and at FIGS. 2A-B and 40A-D.

The Sonnenschein publication, on the other hand, does not describe or suggest a method that includes the recited steps of:

- advancing a main body “comprising a plurality of nested elements” within the hollow body organ;
- transitioning the main body to a rigid state “by imposing a load that clamps the contoured surfaces of adjacent nested elements together;”
- a plication device “extendable from” a distal region of the main body; or
- a plication device comprising “a pair of movable jaws adapted to engage tissue within the hollow body organ.”

The Office Action (at pg. 13) once again identifies the insertion tube 48 of a conventional endoscope 40 described at paragraph 0162 of the Sonnenschein publication as corresponding with the recited main body, and the stapling assembly 61, 61A as corresponding with the recited plication device. Sonnenschein, however, does not describe or suggest that the stapling assembly 61, 61A is “extendable from” a distal region of the endoscope 40. Moreover, the stapling assembly 61, 61A of the Sonnenschein device does not include the recited “pair of movable jaws adapted to engage tissue within the hollow organ.”

The El Gazayerli patent and the Kalloo publication do not correct the deficiencies of the Sonnenschein publication. As discussed in Section A above, neither of these references describes a method that includes the recited steps of advancing a main body having a plication device extendable from a distal region thereof and comprising a pair of movable jaws adapted to engage tissue within the hollow body organ.

Accordingly, because at least these elements recited in claim 43 are not disclosed, taught, or suggested by the Sonnenschein publication or by the combination of Sonnenschein with any of the other cited references, and because the Office Action fails to set forth an appropriate foundation for combining the references in the manner proposed in the Office Action, there can be no prima facie case of obviousness of claim 43. The claim, and all of its dependent claims (i.e., claims 44-49), should be allowed.

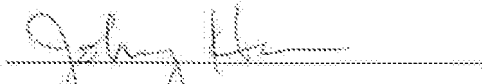
Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, but rather as an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02512**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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